MAR 16 2006

K060484

510K SUMMARY

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Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	Julie Stephens, President/Consultant Regulatory Resources Group, Inc.
Date Prepared:	February 23, 2006
Common Name:	Electrosurgical Generator (ESU) System
Trade/Proprietary Name:	ERBE VIO ESU (Model VIO 300 D)
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Product Code:	GEI
Legally Marketed Predicate Device:	ERBE VIO ESU (Model VIO 300 D) with Accessories 510(k) Number: K023886

Device Description:

The ERBE VIO ESU with Accessories is an electrosurgical system that uses high frequency (HF) electrical current waveforms to cut and/or coagulate tissue. There were no modifications to the Accessories from the previously cleared 510(k) K023886; therefore, they are not included with this submission.

Unit (Model VIO 300 D)

General Description. The ESU has a color monitor display that provides the user with an on-screen tutorial as well as setting and operational information. The unit has various cutting and coagulation modes with defined effect levels to provide the physician flexibility in interventional applications (*i.e.*, its ability to generate HF current). The system has automatic start and stop features. The equipment is programmable and various accessories (*e.g.*, footswitches, hand instruments, etc.) as well as modes may be assigned to perform specific functions. When activated, the device has an audio and visual error system (i.e., malfunctions or user errors are detected with medical personnel being alerted visually and/or by sound with, in some cases, no energy being delivered). Upon activation, the energy delivered (in watts) from the ESU to the tissue is displayed on the display screen. Also, the unit can be used in association with an ERBE compatible Argon Plasma Coagulator (APC). The unit is supplied non-sterile and is reusable.

Note: VIO stands for Variable Cut and Coagulation.

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Indications for Use:

The ERBE VIO ESU with Accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue.

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

ERBE VIO 300 D ESU

Similarities
The modified ESU (ERBE VIO 300 D ESU) has the same protective circuits and intended use as the predicate ESU (ERBE VIO 300 D ESU) and most of the performance specifications are the same. The modified ESU has the same protective circuits as the predicate ESU, which displays the Equipment Output Error on the monitor screen with a graphic representation so that you can readily determine the cause of the error. The modified ESU will also be manufactured by ERBE Elektromedizin GmbH in Germany and will be supplied as a non-sterile, reusable ESU system. The packaging and labeling (User Manual, etc.) components are similar except in the descriptions of specific user instructions.

Monopolar Modes:
The modified ESU has the same cut and coagulation modes, Effect levels, power maximums (wattages) and voltage maximums. The User Manual remains the same in the statement to the physician: "The power output setting should be set as low as possible for the desired tissue affect. The purpose of this is to help reduce the potential for capacitive coupling and inadvertent burning at higher wattages/ voltages."

Bipolar Modes:
The modified ESU has the same cut and coagulation modes, Effect levels, power maximums (wattages) and voltage maximums. The User Manual remains the same in the statement to the physician: "The power output setting should be set as low as possible for the desired tissue affect. The purpose of this is to help reduce the potential for capacitive coupling and inadvertent burning at higher wattages/voltages."

BiClamp, APC, and Argon-Assisted Modes:
The modified ESU has the same cut and coagulation modes, Effect levels, power maximums (wattages) and voltage maximums specific to BiClamp, APC, and Argon-Assisted Modes. The User Manual remains the same in the statement to the physician: "The power output setting should be set as low as possible for the desired tissue affect. The purpose of this is to help reduce the potential for capacitive coupling and inadvertent burning at higher wattages/ voltages."

The ENDO CUT is a function in which the incision is automatically controlled in such a way that alternating short cuts are combined with soft coagulation. Although both of these modes were available on the original 510(k) ESU, the product was not initially launched on the marketplace with this combination function available. The predicate ESU has this feature specified as ENDO CUT I and ENDO CUT Q and has been in use for approximately two years. The modified ESU will continue with these same features except for slight differences as described below.

Differences

Monopolar Modes:
The ENDO CUT function was modified to more consistently emulate the original ENDO CUT technology from the ERBE ICC Series (Models) of ESUs. The ENDO CUT program, "I" (for use with needle instruments), has the same settings as the predicate product. The ENDO CUT program, "Q" (for use with loop instruments), has modified default settings from the predicate product. The control/ regulation of the ENDO CUT Q Mode was improved based on the field experience of the predicate Mode. These modifications do not affect the safety or efficacy of the VIO 300 D ESU. The labeling reflects the changes.

Bipolar Modes:
The modified ESU has two additional modes than in the predicate ESU. Additional modes were added per feedback from the physicians. A Bipolar Cut + mode and a Bipolar Soft Coag + mode were added for greater flexibility of use with Bipolar resection instruments. The addition of these modes does not affect the safety or efficacy of the modified ESU. The labeling reflects the changes.

BiClamp, APC, and Argon-Assisted Modes:
A modification was completed on the internal hardware of the high frequency (HF) generator printed circuit board (PCB). An additional decoupling capacitor was added on the HF-generator board to reduce the neuromuscular stimulation (NMS) effect during APC Pulsed Mode usage. Many of the gastrointestinal (GI) operative procedures are completed under minimal usage of anesthesia; therefore, the additional capacitor will assist in reduction of NMS during the usage of the APC Pulsed Mode. While NMS is a known issue with all high frequency electrical current generators, the APC Pulsed Mode is ideal for some operative procedures and the addition of the capacitor lowers the susceptibility of patients to NMS during use of the mode.

All the unit modifications have been verified or validated in design control.

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Conclusion:

The ERBE VIO ESU (Model VIO 300 D) has the same intended use, principles of operation, and technological characteristics as the predicate ESU in the previously cleared 510(k). The main modifications in the ESU reflect an ongoing commitment by ERBE to satisfy customer feedback. In conclusion, there are no issues with the ERBE VIO ESU (Model VIO 300 D) that would raise additional safety or efficacy issues when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

ERBE USA, Incorporated
c/o Regulatory Resources Group, Inc.
Ms. Julie Stephens
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K060484
Trade/Device Name: ERBE USA Inc. – ERBE VIO ESU (Model VIO 300 D)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 23, 2006
Received: February 27, 2006

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060484

Device Name: ERBE USA Inc. - ERBE VIO ESU (Model VIO 300 D)

Indications For Use:

The ERBE VIO ESU with Accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060484